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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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VELIO MALLOZZI and ROSALIE MALLOZZI,

Plaintiffs,

-against-

ECOSMART TECHNOLOGIES, INC.,

Defendant.
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OPINION AND ORDER
11-CV-2884 (SJF)(ARL)

FEUERSTEIN, J.

On June 15, 2011, plaintiffs Velio Mallozzi ("plaintiff") and Rosalie Mallozzi commenced this action against EcoSMART Technologies, Inc. ("defendant"), asserting claims arising from plaintiff's use of a pest control product manufactured and distributed by defendant, including (1) negligence, (2) breach of express and implied warranties, (3) strict liability, and (4) loss of consortium. [Docket Entry No. 1] ("Compl."). Now before the Court is defendant's motion for summary judgment dismissing the complaint pursuant to Rule 56 of the Federal Rules of Civil Procedure. [Docket Entry No. 16] (the "motion"). For the reasons that follow, the motion is GRANTED.

I. Background

A. Exposure to the Product

On April 19, 2010, over the course of approximately ten (10) minutes, plaintiff applied "a couple of ounces" of EcoSmart Organic Home Pest Control (the "product") to the foundation of his home and a "couple of spray[s]" inside his home. Declaration of Joseph M. Tomaino ("Tomaino Dec.") Ex. G [Docket Entry No. 16-3] ("Mallozzi Dep.") at 37:06-22, 38:07-08, 40:05-10, 42:06-17; Compl. at ¶¶ 15, 18. The product contains various plant oils, including one

percent (1.00%) peppermint oil, Defendant's Rule 56.1 Statement [Docket Entry No. 16-7] at ¶¶ 1-3,[1] and plaintiff alleges that "his inhalation of the product's spray mist, and in particular the peppermint oil ingredient in the product, caused him to develop a condition known as Laryngopharyngeal Reflux ('LPR'), which involves the constant backflow of stomach contents into the throat," Plaintiff's Memorandum of Law in Opposition to the Motion for Summary Judgment [Docket Entry No. 16-10] ("Pl. Memo.") at 1.

Plaintiff left his home after spraying the product and did not experience any immediate adverse effects from his exposure. Mallozzi Dep. at 40:07-10, 42:18-25. Later that night, following dinner at an Italian restaurant, plaintiff felt "a little bit nauseous and [his] heart was pumping very fast and [he] fe[lt] like throwing up." Id. at 47:15-21. When he returned home after dinner, he could smell the product and had trouble sleeping due to burning in his stomach and chest. Id. at 46:16-47:02, 49:22-50:17. The following morning, plaintiff continued to experience "burning [in his] stomach, all the way up to [his] throat." Id. at 49:19-21.

B. Medical Treatment

On April 23, 2010, plaintiff went to a walk-in clinic and was diagnosed with "Tracheritis" and given a prescription for Prednisone. Declaration of Michael S. Levine in

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[1] "Rule 56.1 of the Local Civil Rules of the United States District Courts for the Southern and Eastern Districts of New York [("Rule 56.1")] requires a party moving for summary judgment to submit a statement of the allegedly undisputed facts on which the moving party relies, together with citation to the admissible evidence of record supporting each such fact." Giannullo v. City of N.Y., 322 F.3d 139, 140 (2d Cir. 2003). The "party opposing summary judgment must respond with a statement of facts as to which a triable issue remains. The facts set forth in a moving party's statement will be deemed to be admitted unless controverted by the opposing party's statement." Holtz v. Rockefeller & Co., Inc., 258 F.3d 62, 73 (2d Cir. 2001). Plaintiff failed to submit a Rule 56.1 statement. Therefore, the few facts set forth in defendant's Rule 56.1 statement are accepted as true. Plaintiff's "Counter-Statement of the Case" included in his memorandum in opposition to defendant's motion has been considered by the Court to the extent it is supported by evidence in the record and is not contradicted by defendant's Rule 56.1 statement.

Opposition to Motion for Summary Judgment [Docket Entry No. 16-11] ("Levine Dec.") Ex. 2. On April 26, 2010, plaintiff went to the emergency room, complaining of "coughing up phlegm, reflux-like burning, and hoarseness," and "underwent an indirect laryngoscopy and a cervical-thoracic esophogram." Pl. Memo. at 4; Levine Dec. Ex. 3. On September 8, 2010, plaintiff underwent another cervical-thoracic esophogram, which showed "severe gastroesophageal reflux disease ["GERD"] with contrast readily reaching the level of the mouth." Levine Dec. Ex. 4. Plaintiff returned to the hospital for further tests and procedures on September 27 and 28, 2010. Pl. Memo. at 4. Plaintiff's treating physician at the hospital, Dr. Gina Sam, diagnosed plaintiff with "laryngeal edema due to reflux." Levine Dec. at Ex. 5.

In addition to his visits to the hospital, plaintiff was treated by Dr. Philip Mantia on April 28, 2010, June 15, 2010 and September 20, 2010. Pl. Memo. at 4. On April 28, 2010, Dr. Mantia diagnosed plaintiff with "chemical burn" and laryngitis. Levine Dec. at Ex. 6; Report of Barry S. Levy, M.D. [Docket Entry No. 16-4] ("Levy Report") at 3. Dr. Mantia referred plaintiff to a otolaryngologist, Dr. Anna Stern, who diagnosed plaintiff with: (1) acute laryngitis "from inhaled chemicals" on April 30, 2010; (2) "[e]rythema/edema improved[] now with significant hyperfunction" on May 14, 2010; (3) "[e]rythema/edema" and muscle tension dysphonia ("MTD") on May 26, 2010; (4) "acute tonsillitis . . . likely viral" and "lymphadenitis" on July 9, 2010; (5) chronic laryngitis and gastroesophageal reflux on August 11, 2010; and (6) dysphonia, "worsening of MTD" and gastroesophageal reflux on September 1, 2010. Levine Dec. Ex. 7; Levy Report at 3-4.

On June 28, 2010, plaintiff was seen by Linda Cocchiarella, a doctor at the Long Island Occupational and Environmental Health Center, who diagnosed plaintiff with laryngitis, "secondary to chemical irritation and reflux following exposure to pesticide," and GERD, stating

that "[t]he peppermint oil in the insecticide likely contributed to or caused his reflux as peppermint oil promotes relaxation of the lower esophageal sphincter." Levine Dec. Ex. 8.[2] On November 17, 2010, Dr. Cocchiarella diagnosed plaintiff with (1) "Laryngitis and pharyngitis – following exposure to pesticide," and (2) "GERD, gastritis, [and] esophagitis." Levine Dec. Ex. 9. On January 19, 2011, February 8, 2011 and February 28, 2011, plaintiff complained to Dr. Cocchiarella that he continued to "have belching and reflux daily," and Dr. Cocchiarella diagnosed "Laryngitis and pharyngitis – with ongoing reflux, developed following exposure to pesticide." Id. Dr. Cocchiarella further stated that the "[e]pisode [was] precipitated by exposure to eco smart organic insect killer . . . which had peppermint which can increase reflux." Id. On March 28, 2011, Dr. Cocchiarella characterized plaintiff's hiatal hernia as "stable." Id.[3]

II. Summary Judgment Standard

"Summary judgment must be granted where the pleadings, the discovery and disclosure materials on file, and any affidavits show 'that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" Brown v. Eli Lilly & Co., 654 F.3d 347, 358 (2d Cir. 2011) (quoting Fed. R. Civ. P. 56(a)). "In ruling on a summary judgment motion, the district court must resolve all ambiguities, and credit all factual inferences that could rationally be drawn, in favor of the party opposing summary judgment and determine whether there is a genuine dispute as to a material fact, raising an issue for trial." McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 202 (2d Cir. 2007) (internal quotation marks omitted). "A fact is material if it might affect the outcome of the suit under the governing law, and an issue

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[2] Dr. Levy's report erroneously states that the examination on June 28, 2010 was conducted by Dr. Mantia. See Levy Report at 4.

[3] Plaintiff's medical history prior to his exposure to the product is discussed in further detail below.

of fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Ramos v. Baldor Specialty Foods, Inc., 687 F.3d 554, 558 (2d Cir. 2012) (internal quotation marks omitted). "There is no genuine issue of material fact where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party." Fabrikant v. French, 691 F.3d 193, 205 (2d Cir. 2012) (internal quotation marks omitted).

"The moving party bears the burden of establishing the absence of any genuine issue of material fact." Zalaski v. City of Bridgeport Police Dep't, 613 F.3d 336, 340 (2d Cir. 2010). If this burden is met, "the opposing party must come forward with specific evidence demonstrating the existence of a genuine dispute of material fact." Brown v. Eli Lilly & Co., 654 F.3d 347, 358 (2d Cir. 2011). The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts and may not rely on conclusory allegations or unsubstantiated speculation." Id. (internal quotation marks and citations omitted).

III. Analysis

In order to prevail in this action, whether on a negligence or strict liability theory, plaintiff must show that his exposure to the product was the proximate cause of his injuries. See, e.g., Caronia v. Philip Morris USA, Inc., --- F.3d ---, 2013 WL 1810843, at *9 (2d Cir. May 1, 2013) ("Under New York law, in order to recover on a claim for negligence, a plaintiff must show '(1) the existence of a duty on defendant's part as to plaintiff; (2) a breach of this duty; and (3) injury to the plaintiff as a result thereof.'") (quoting Akins v. Glens Falls City Sch. Dist., 441 N.Y.S.2d 644, 648 (1981)); id. at *5 ("A plaintiff asserting a claim of strict liability must be able to show that she was injured, that the defendant produced a product that was not reasonably safe for its intended use, and that the product's defect was the proximate cause of the injury.") (internal quotation marks omitted); Hollman v. Taser Int'l Inc., --- F. Supp.2d --- , 2013 WL

864538, at *11 (E.D.N.Y. Mar. 8, 2013) ("Under New York law, in order to make a prima facie case for failure to warn, a plaintiff must show the following: (1) the manufacturer had a duty to warn; (2) the manufacturer breached the duty to warn in a manner that rendered the product defective, i.e., reasonably certain to be dangerous; (3) the defect was the proximate cause of the plaintiff's injury; and (4) the plaintiff suffered loss or damage."). "Under New York law, when the determination of whether an illness or injury was caused by some event or conduct is 'presumed not to be within common knowledge and experience,' a plaintiff must produce expert opinion evidence 'based on suitable hypotheses' in order to support a finding of causation." Amorgianos v. Nat'l R.R. Passenger Corp., 137 F. Supp.2d 147, 160 (E.D.N.Y. 2001), aff'd, 303 F.3d 256 (2d Cir. 2002) (quoting Meiselman v. Crown Heights Hosp., 285 N.Y. 389, 396 (1941)); see also Fane v. Zimmer, Inc., 927 F.2d 124, 131 (2d Cir. 1991) ("The issue of causation in such a complicated medical case, therefore, was one beyond the sphere of the ordinary juryman and required expert testimony."); Wills v. Amerada Hess Corp., 379 F.3d 32, 46 (2d Cir. 2004) ("In a case such as this, where an injury has multiple potential etiologies, expert testimony is necessary to establish causation . . . ."). Plaintiff does not dispute that the causation issue presented in this case is beyond the purview of the ordinary layperson and requires expert testimony.

To establish causation in this case, plaintiff "must offer admissible expert testimony regarding both general causation, i.e., that [the] exposure can cause the type of ailments from which [the plaintiff] claims to suffer; and specific causation, i.e., that [the] exposure caused his alleged" injuries. Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 268 (2d Cir. 2002). "General causation bears on whether the type of injury at issue can be caused or exacerbated by the defendant's product," while "'[s]pecific' causation bears on whether, in the particular

instance, the injury actually was caused or exacerbated by the defendant's product." Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 251 n.1 (2d Cir. 2005) (citing Amorgianos, 303 F.3d at 268); see also Mancuso v. Consol. Edison Co. of N.Y., Inc., 967 F. Supp. 1437, 1445 (S.D.N.Y. 1997) ("[T]he expert must establish 'general causation,' by demonstrating that, according to scientific literature, levels of the toxin comparable to those received by the plaintiff can cause the specific types of injuries he alleges. . . . [T]he expert must establish specific causation, by demonstrating that, more likely than not, the toxin caused the plaintiff's injuries in this particular case.").

Plaintiff relies upon the opinion of Dr. Barry S. Levy, an occupational and environmental health physician and epidemiologist, that plaintiff's "exposure to peppermint oil in [the product], starting on April 19, 2010, caused his laryngopharyngeal reflux, by relaxing his lower esophageal sphincter." Levy Report at 12-13; Pl. Memo. at 6. Defendant argues that Dr. Levy's testimony is unreliable and does not meet the standard imposed by Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), because Dr. Levy "lacks the necessary facts regarding peppermint oil to establish dose, method of exposure (inhalation versus ingestion), general acceptance in the medical community and any long-term health risk." Defendant's Memorandum of Law in Support of Its Motion for Summary Judgment [Docket Entry No. 16-6] at 6.

Rule 702 of the Federal Rules of Evidence ("Rule 702") "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable.'" Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (omission in original) (quoting Daubert, 509 U.S. at 589); see also United States v. Farhane, 634 F.3d 127, 158 (2d Cir. 2011) ("The law assigns district courts a 'gatekeeping' role in ensuring that expert testimony

satisfies the requirements of Rule 702."); United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007) ("While the proponent of expert testimony has the burden of establishing by a preponderance of the evidence that the admissibility requirements of Rule 702 are satisfied, the district court is the ultimate 'gatekeeper.'") (citation omitted). To determine if Dr. Levy's "proffered testimony has a sufficiently reliable foundation to permit it to be considered," the Court must consider whether: (1) the testimony is grounded on sufficient facts or data; (2) the testimony is the product of reliable principles and methods; and (3) Dr. Levy has applied the principles and methods reliably to the facts of the case. Amorgianos, 303 F.3d at 265 (internal quotation marks omitted) (citing FED. R. EVID. 702). Although "[t]he inquiry is a flexible one, and district courts enjoy considerable discretion in deciding on the admissibility of expert testimony," Farhane, 634 F.3d at 158 (citation omitted), "[t]he Supreme Court has identified a number of factors bearing on reliability that district courts may consider, such as (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) a technique's known or potential rate of error, and the existence and maintenance of standards controlling the technique's operation; and (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community," Amorgianos, 303 F.3d at 266 (citing Daubert, 509 U.S. at 593-94) (internal quotation marks omitted).

A. General Causation

According to Dr. Levy, in reaching his conclusion regarding general causation he (1) "searched for and systematically reviewed publications concerning peppermint oil and its health effects," (2) "reviewed the body of relevant medical and scientific literature as a whole and applied the Bradford Hill principles," and (3) "reviewed literature pertaining to [LPR]."

Levy Report at 2; Tomaino Dec. Ex. O ("Levy Dep.") at 46:09-47:04.

A Bradford Hill analysis is applied by epidemiologists to determine whether a causal relationship exists between two (2) events. See In re Joint Eastern & Southern Dist. Asbestos Litig., 52 F.3d 1124, 1128 (2d Cir. 1995) (citing A. Bradford Hill, The Environment and Disease: Association or Causation, 58 PROC. ROYAL SOC'Y MED. 295, 295-300 (1965)). The "analysis requires looking at nine criteria including: temporal relationship, strength of association, dose-response relationship, replication of the findings, biological plausibility, consideration of alternative explanations, cessation of exposure, specificity of the association, and consistency with other knowledge." Deutsch v. Novartis Pharm. Corp., 768 F. Supp.2d 420, 454 (E.D.N.Y. 2011). "Several courts that have considered the question have held that it is not proper methodology for an epidemiologist to apply the Bradford Hill factors without data from controlled studies showing an association." In re Fosamax Prod. Liab. Litig.,, 645 F. Supp.2d 164, 188 (S.D.N.Y. 2009). Although Dr. Levy states that he "applied the Bradford Hill principles to determine general causation," he has not included any discussion of his analysis and instead lists four (4) articles relating to peppermint oil which he purportedly relied upon in reaching his conclusion. Levy Report at 8-9; Pl. Memo. at 6; Levy Dep. at 43:16-17 ("Specifically with regard to peppermint oil, I relied on these four papers."). These articles do not provide a reliable basis for Dr. Levy's opinion because they do not address in any manner whether inhalation of a substance containing one percent (1.00%) peppermint oil, over the course of a matter of minutes, can relax the lower esophageal sphincter or cause LPR. Amorgianos, 137 F. Supp.2d at 163 ("[I]n a toxic tort case, expert testimony on the issue of general causation meets Daubert's 'fit' requirement only if the testimony includes an opinion that (1) exposure to the particular substance at issue, (2) in the dose to which the plaintiff was exposed, (3) for the

duration in which plaintiff was exposed, (4) can cause the particular condition(s) of which the plaintiff complains."); see also, e.g., Levy Dep. at 75:21-76:06 ("Q: Doctor, the four articles that you reference regarding peppermint oil, they all deal with patients who ingested peppermint oil, correct? A: They all, at least in part, dealt with ingestion. Q: Do any of them deal with inhalation specifically? A: None of the four articles specifically deal with inhalation of peppermint oil."); id. at 88:11-25 ("Q: Do any of the articles you cite regarding LPR reference peppermint oil? . . . A: I don't recall any of the articles specifically referencing peppermint oil. None of the articles on LPR in my files, but most, if not all, the articles do not address the issue of the causation or contributing factors to the reflux of stomach contents of the esophagus to the larynx.").

The first article, M.H. Pittler, E. Ernest, Peppermint Oil for Irritable Bowel Syndrome: A Critical Review and Metaanalysis, 93 AMERICAN JOURNAL OF GASTROENTEROLOGY 1131, 1131-1135 (1998) is "a review [of] clinical trials of extracts of peppermint . . . as a symptomatic treatment for irritable bowel syndrome." The article states that eleven (11) to thirty-six (36) percent of the patients in the clinical studies reported adverse drug reactions while taking peppermint oil, including "[h]eartburn, perianal burning, blurred vision, nausea, and vomiting," and that "peppermint oil has been shown to relax isolated gastrointestinal smooth muscle of both animal . . . and human . . . coli." Id. at 1133-34; Levy Report at 8. Although a finding that peppermint oil relaxes gastrointestinal smooth muscle would support the plausibility of Dr. Levy's opinion that it can relax the lower esophageal sphincter, the article does not describe the studies supporting this finding and Dr. Levy has not shown that it is applicable to the circumstances of plaintiff's exposure. Moreover, the clinical studies actually reviewed in the article, which showed that peppermint oil may have adverse effects on the gastrointestinal

system (including heartburn) are not applicable to this case because they involved patients ingesting enteric-coated capsules on a regular basis over the course of two (2) to six (6) weeks (one (1) of the eight (8) trials lasted six (6) months). Id. at 1132. The studies did not address inhalation of small amounts of peppermint oil or its effect on the lower esophageal sphincter and do not support the contention that inhalation (or ingestion) of peppermint oil can cause LPR, i.e., "the constant backflow of stomach contents into the throat," Pl. Memo. at 1.

The second article, H.G. Grigoleit, P. Grigoleit, Gastrointestinal Clinical Pharmacology of Peppermint Oil, 12 PHYTOMEDICINE 607, 607-611 (2005), is a review of nine (9) studies where two hundred sixty-nine (269) "healthy subjects or patients underwent exposure to peppermint oil . . . either by topical, intraluminal (stomach or colon), or oral administration by single doses or 2 weeks treatment." The article reports that the studies found "a substantial spasmolytic effect of [peppermint oil] on the smooth muscles of the gastrointestinal tract," id. at Abstract, and "evidence that the typical adverse events of [peppermint oil] (e.g. heartburn) do occur if [peppermint oil] is released in the upper gastrointestinal tract" id. at 610. This article again does not address inhalation of peppermint oil or its effect on the lower esophageal sphincter and the development of LPR. Furthermore, the article undermines the position that peppermint oil can have persistent adverse effects on the gastrointestinal system, stating that the "spasmolytic effect" of peppermint oil "is limited to approximately 20 min[utes]." Id. at 610.[4]

The third article, S. Tamir, Z. Davidovic, P. Attal, R. Eliashar, Peppermint Oil Chemical Burn, 133 OTOLARYNGOLOGY – HEAD AND NECK SURGERY, 801-02 (2005), a case report of a woman who ingested "forty (40) drops of pure nonheated peppermint oil," reported that the patient suffered "multiple burns in her oral cavity and pharynx, and edema of her lips, tongue,

[4] Dr. Levy omitted the temporal qualification of the article's findings from his report.

uvula, and soft palate[,] . . . a red and swollen epiglottis, and hypopharyngeal and laryngeal mucosal burns." Id.; Levy Report at 9. A case report relating to chemical burns caused by the ingestion of large amounts of pure peppermint oil has no relevance to the issue presented here. Furthermore, even if the case report was analogous to plaintiff's experience, it is not clear that a single case report can provide a reliable basis for a general causation opinion. See, e.g., In re Neurontin Mktg., Sales Practices, and Prods. Liab. Litig., 612 F. Supp.2d 116, 127 (D. Mass. 2009) ("Case reports lack controls and thus do not provide as much information as controlled epidemiological studies do.") (internal quotation marks omitted); Deutsch, 768 F. Supp.2d at 476 ("Even if case reports on their own are not reliable evidence of causation, they do contribute to the reliability of a causation determination.").

The fourth article, B. Kligler, S. Chaudhary, Peppermint Oil, 75 AMERICAN FAMILY PHYSICIAN 1027, 1027-1030 (2007), reviewed clinical studies on: (1) the ingestion of enteric-coated peppermint oil as a treatment for irritable bowel syndrome; (2) the use of a combination product including peppermint oil and caraway oil as a treatment for non-ulcer dyspepsia; (3) topical application of peppermint oil as a treatment for headaches; and (4) the use of peppermint oil given by enema as a treatment for colonic spasm. The article states that "[p]eppermint oil is relatively contraindicated in patients with hiatal hernia or significant gastroesophageal reflux disease, because its effect on the lower esophageal sphincter can lead to exacerbation of symptoms." Id. at 1029-30; Levy Report at 9.

Dr. Levy concludes from the this article that "people who have hiatal hernia or significant gastroesophageal reflux disease should not be exposed to peppermint oil." Levy Dep. at 71:17-72:08. Dr. Levy provided no analysis of, and apparently did not review, the clinical trials that were reviewed in the article, see Levy Dep. at 43:16-17, and therefore has not justified his

reliance on the article's statement that peppermint oil is relatively contraindicated in patients with a hiatal hernia or GERD. Furthermore, Dr. Levy has not offered any basis for extending this contraindication to the inhalation of a substance containing one percent (1.00%) peppermint oil. The clinical trials reviewed in the article did not consider inhalation of peppermint oil, but rather involved: (1) patients ingesting enteric-coated capsules with a "dosage range . . . [of] 0.2 to 0.4 mL of peppermint oil taken three times daily" over the course of a number of weeks; (2) ingestion of a "dose of 90 mg of peppermint oil in combination with 50 mg of caraway oil"; (3) topical application of peppermint oil; and (4) peppermint oil given via enema. Id. at 1029-30. Dr. Levy has failed to provide any support for the proposition that a single incident of inhalation of a substance containing one percent (1.00%) peppermint oil affects the lower esophageal sphincter in the same manner as topical application or regular ingestion of enteric-coated peppermint oil pills. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 144-47 (1997) (affirming the district court's exclusion of expert testimony which relied upon animal studies where the subject animals were exposed to the chemical in question at a much higher concentration and different manner than the plaintiff); Amorgianos, 137 F. Supp.2d at 183 ("None of the four review articles discusses xylene specifically, and none provides any conclusion as to the dose or duration of exposure to any particular organic solvent required to produce chronic . . . effects. Moreover, the underlying studies cited by the authors of these review articles reveal exposure histories very different from [the plaintiff's].") (citation omitted).

Although "[g]eneral acceptance in the relevant scientific community . . . is no longer determinative," McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1042 (2d Cir. 1995), the Court must nonetheless make an "assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be

applied to the facts in issue," Daubert, 509 U.S. at 592-93. The literature relied upon by Dr. Levy, even if it supports the proposition that peppermint oil may adversely affect the gastrointestinal system when ingested or applied topically, does not support his opinion that the brief inhalation of a substance containing one percent (1.00%) peppermint oil can cause LPR. Dr. Levy's analysis ignores the importance of (1) dose, (2) duration of exposure, (3) means of exposure, and (4) the relationship between the chemical and plaintiff's particular condition (LPR). See Levy Dep. at 59:06-08 ("I don't have a quantitative measure of the amount of product that he used at that time."); id. at 62:14-17 ("Q: Do you have any idea how much peppermint oil this gentleman was exposed to over the period of time in question? A: I have not quantitated that."); see also, e.g., See Joiner, 522 U.S. at 146-47 ("[B]ecause it was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions that [the plaintiff's] exposure to PCB's contributed to his cancer, the District Court did not abuse its discretion in excluding their testimony."); Amorgianos, 137 F. Supp.2d at 177-178 ("The issue in this case is not whether exposure to some organic solvent in some dose and for some duration can cause some effect of some duration . . . . The issue is whether exposure to xylene in the amount and for the duration alleged by plaintiffs can cause . . . symptoms of the type, magnitude, and duration allegedly suffered by [the plaintiff]. The medical evidence on which plaintiffs' experts rely, of course, need not precisely match the specifics of this case in those respects, but it must at least be in the same ballpark."). Therefore, plaintiff has failed to demonstrate that Dr. Levy's general causation opinion is grounded on sufficient facts or data and is the product of reliable principles and methods as required by Rule 702.

B. Specific Causation

According to Dr. Levy, he reached his opinion on specific causation by: (1) reviewing plaintiff's (a) "diagnosis of laryngopharyngeal reflux," (b) medical history, and (c) exposure history; (2) performing a "differential etiology analysis, in which [he] considered other plausible causes of and contributing factors to [plaintiff's] LPR"; (3) considering latency; and (4) "synthesiz[ing] all of [the foregoing] information." Levy Report at 2.[5] A differential etiology analysis, or "differential diagnosis," is "a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." Ruggiero, 424 F.3d at 254 (internal quotation marks omitted). "A medical expert's opinion based upon differential diagnosis normally should not be excluded because the expert has failed to rule out every possible alternative cause of a plaintiff's illness." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001). However, even though "an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel v. Spring Indus., Inc., 98-CV-5106, 2006 WL 3196956, at *5 (E.D.N.Y. Nov. 3, 2006). A review of the record demonstrates that Dr. Levy did not have a sufficient basis to conduct a reliable differential diagnosis here, and therefore his specific causation opinion must be excluded.[6]

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[5] The Bradford-Hill factors are used to establish general causation, not specific causation. See, e.g., In re Viagra Prods. Liab. Litig., 658 F. Supp.2d 950 958 (D. Minn. 2009) ("[T]he Bradford Hill criteria are used to establish general causation from epidemiological studies—they are not used to establish specific causation."); Wells v. SmithKline Beecham Corp., No. A-06-CA-126, 2009 WL 564303, at *5 (W.D. Tex. Feb. 18, 2009) ("Epidemiology can be used to prove general causation, but not specific causation.").

[6] A differential diagnosis may be admissible even in the absence of definitive support for the diagnosis in the scientific literature if the diagnosis is otherwise reliable. See, e.g.,

1. Dose and Duration

Dr. Levy has expressed no opinion with regard to the amount of peppermint oil inhaled by plaintiff as a result of his use of the product. According to plaintiff, "[w]hile precise information regarding how much peppermint oil was sprayed and became airborne so that the plaintiff could inhale it is not available, and will never be, the plaintiff is not required to show such precise information to survive summary judgment." Pl. Memo. at 10. In support of this argument, plaintiff relies upon Westberry v. Gislaved Gummi AB, 178 F.3d 257 (4th Cir. 1999), Heller v. Shaw Indus., 167 F.3d 146 (3d Cir. 1999), and Bonner v. ISP Techs., Inc., 259 F.3d 924 (8th Cir. 2001). The differential diagnoses performed in these cases are easily distinguishable from Dr. Levy's analysis.

In Westberry, the defendant challenged the trial court's admission of the opinion testimony of the plaintiff's treating physician that the plaintiff's inhalation of talcum powder (placed on gaskets manufactured by the defendant) proximately caused the aggravation of his pre-existing sinus condition. 178 F.3d at 259-60. The Fourth Circuit held that, in general, "a reliable differential diagnosis provides a valid foundation for an expert opinion," id. at 263, and that the expert's diagnosis was admissible because, inter alia, it was "clearly [] not a case in which the plaintiff was unable to establish any substantial exposure to the allegedly defective

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McCullock, 61 F.3d at 1043-44 (affirming admission of treating doctor's diagnosis where he "based his opinion on a range of factors, including his care and treatment of [the plaintiff]; her medical history . . . ; pathological studies, review of [the defendant's] MSDS; his training and experience; use of a scientific analysis known as differential etiology . . . ; and reference to various scientific and medical treatises," but "could not point to a single piece of medical literature that says glue fumes cause throat polyps"); Heller, 167 F.3d 146, 154 (3d Cir. 1999) ("[W]e do not believe that Daubert and Paoli require a physician to rely on definitive published studies before concluding that exposure to a particular object or chemical was the most likely cause of a plaintiff's illness. Both a differential diagnosis and a temporal analysis, properly performed, would generally meet the requirements of Daubert and Paoli."). Because Dr. Levy did not perform a reliable differential diagnosis, it is not necessary for the Court to determine whether such a diagnosis would overcome the absence of scientific support in this case.

product." Id. at 265. "[A]lthough [the physician] did not point to [the plaintiff's] exposure to a specific level of airborne talc, there was evidence of a substantial exposure." Id. at 265.[7] Here, on the other hand, there is no evidence that plaintiff experienced "substantial exposure" to peppermint oil, and therefore the level and duration of exposure is crucial. See Amorgianos, 137 F. Supp.2d at 168-69 ("The toxicity of any substance depends critically on the dose to which a human being is exposed and for what duration. Thus, in order for the jury to evaluate the hypothesis that [the plaintiffs'] alleged illness could be caused by his level of exposure to [the chemicals], [the] plaintiffs must establish what that exposure was in terms of dose and duration.") (citation omitted).

Likewise, in Bonner, the Eighth Circuit held that "it was not necessary that [the plaintiff's] experts quantify the amount of [the product] to which she was exposed in order to demonstrate that she was exposed to a toxic level of [the chemical]" because "[i]t is sufficient for a plaintiff to prove that she was exposed to a quantity of toxin that 'exceeded safe levels.'" 259 F.3d at 931. Therefore, the precise level of exposure was held to be immaterial in Bonner only because it was established that the plaintiff's exposure "exceeded safe levels," and the court specifically relied upon the fact that the plaintiff "presented witnesses who testified that her exposure to [the product] was of a duration and of a volume sufficient to support a conclusion that she inhaled and/or absorbed through her skin at least a quarter of a teaspoon of [the product] when she was sprayed with it." Id. Here, Dr. Levy is unable to even approximate the volume or duration of plaintiff's exposure and therefore cannot reliably opine that the quantity of peppermint oil inhaled by plaintiff "exceeded safe levels."

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[7] The court in Westberry also noted that, unlike in this case, there was no dispute as to general causation. 178 F.3d at 265 ("[T]here was no dispute that exposure to high concentrations of airborne talc could cause irritation to mucous membranes.").

In Heller, the Third Circuit held that the district court erred by requiring "as a prerequisite to admissibility" that the expert's testimony "be backed by scientific studies linking the type and level of [the chemicals] detected in the [plaintiff's] home to [the plaintiff's] illness." 167 F.3d at 158. The court further stated that "even absent hard evidence of the level of exposure to the chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff's illness." 167 F.3d at 157 (citing Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 808 (3d Cir. 1997) (rejecting the district court's conclusion that an ambient air test was necessary to determine the plaintiff's degree of exposure to pesticides applied in his home and holding that the expert could rely upon his "review of [the exterminator's] application records, showing when, how much, and where pesticide had been applied")). However, the Third Circuit made clear that the differential diagnosis must nonetheless rest upon a reliable alternative basis and affirmed the district court's exclusion of the expert testimony due to the weakness of the temporal connection between the plaintiff's exposure and illness, which was heavily relied upon by the expert in finding causation. Id. at 157-58. As in Heller, the alternative bases for Dr. Levy's differential diagnosis (such as temporal proximity) are unreliable and cannot compensate for the lack of information regarding dose and duration.

2. Temporal Proximity

Dr. Levy relies heavily on the temporal proximity between plaintiff's exposure to the product and the onset of his symptoms. However, the temporal proximity (several hours) is unconvincing in light of the fact that plaintiff did not experience any adverse effects immediately after his exposure to the product, but rather began experiencing reflux hours later after dining out at an Italian restaurant. The intervening meal ("spaghetti with seafood," Mallozzi Dep. 43:14-15) is significant in light of plaintiff's medical history, which includes recurring GERD that was

at times so severe as to require his hospitalization. Plaintiff was hospitalized in 2001 for esophageal reflux "after eating a donut and drinking coffee," Tomaino Dec. Ex. I, and when asked whether he had ever experienced problems with reflux prior to April 2010, the only incident plaintiff recalled was a time after he "went out to eat . . . and [] had linguini with clam sauce." Mallozzi Dep. at 57:16-23. Dr. Levy has failed to offer an explanation for the delay in the onset of plaintiff's symptoms and, as discussed in further detail below, has failed to justify his dismissal of the intervening meal as an alternative cause of plaintiff's reflux on April 19, 2010.

The significance of temporal proximity here is further lessened by the persistence of plaintiff's symptoms for months after his exposure to the product. See, e.g., Heller, 167 F.3d at 157-58 (stating that "a physician's diagnosis, based in part on a strong temporal relationship between symptoms and exposure, need not necessarily be supported by a statistically significant correlation," but holding that the temporal relationship between the plaintiff's exposure and the onset of illness was "questionable at best and exculpatory at worst" because the plaintiff's symptoms did not appear until one (1) or two (2) weeks after exposure and they remained after the carpet containing the chemicals was removed) (internal quotation marks omitted). Dr. Levy acknowledges that plaintiff's brief exposure could not have caused his persistent reflux over the course of subsequent months and attempts to narrowly limit the scope of his opinion. Dr. Levy testified at his deposition as follows:

> Q: It is referenced numerous times in the medical records after April 2010 where he is complaining of reflux symptoms like heartburn, weeks or months after April of 2010. Can you attribute those reflux complaints and heartburn complaints to the relaxation of the lower esophageal sphincter in April of 2010?
>
> A: My focus of attention in this case was determining the cause of Mr. Mallozzi's laryngeal problem that began on or about April 19, 2010. I have not expressed an opinion, nor do I have an opinion that his continuing GERD symptoms after April

19, 2010 were due to the exposure to peppermint oil.

Q: You attribute the hoarseness in his throat and vocal cord damage to the exposure of the peppermint oil?

A: Yes . . . .

Q: The hoarseness of the voice, the damage to the vocal cords; that's the direct result of the exposure of April of 2010 within a reasonable degree of medical and scientific –

A: Yes, that is basically correct. I have not expressed an opinion; I am not offering an opinion right now that any GERD symptoms that he experienced subsequent to the exposure on April 19, 2010 or started on that date were related to that exposure."

Levy Dep. 98:11-99:22. Dr. Levy's testimony fails to provide a reasonable explanation for his heavy reliance upon the fact that plaintiff experienced reflux on the same day that he used the product. Plaintiff had a long history of problems with reflux prior to his inhalation of the product, including severe episodes following meals, and his GERD problems persisted long after his exposure. Under these circumstances, temporal proximity is not a reliable basis for a differential diagnosis. See In re Fosamax Prod. Liab. Litig., MDL No. 1789, 2009 WL 4042769, at *7 (S.D.N.Y. Nov. 23, 2009) ("A strong temporal relationship between the injury and its alleged cause may be one of several factors considered by a medical doctor to reliably determine causation, but, standing alone, relying wholly on a temporal relationship is not sound scientific methodology that is admissible under Rule 702 and Daubert.").

3. Other Potential Causes

Dr. Levy's testimony is also inadmissible because he has failed to adequately explain his dismissal of other possible causes of plaintiff's injuries. See, e.g., In re Zyprexa Prod. Liab. Litig., No. 04 MD 1596, 2009 WL 1357236, at *2 (E.D.N.Y. May 12, 2009) ("A medical expert must adequately consider possible alternative causes of an alleged disease, avoiding speculative

analysis that automatically implicates a drug in the temporal chain."). Dr. Levy acknowledges that plaintiff had a history of GERD and a hiatal hernia but states that his "opinion reflects the fact that [he] believe[s] that [plaintiff's] exposure to peppermint oil increased the reflux of stomach contents up his esophagus such that they reached his larynx causing the [LPR] problems." Levy Dep. at 97:20-98:05. Dr. Levy stated that "[i]t is precisely because [] plaintiff has pre-existing gastroesophageal reflux disease . . . that he was made more susceptible to experiencing regurgitation of his stomach contents into his esophagus and then into his larynx due to his exposure to the peppermint oil in the defendant's product." Pl. Memo. at 7. However, Dr. Levy has failed to justify his conclusion that reflux specifically caused by inhalation of the product caused plaintiff's LPR and not reflux caused by plaintiff's persistent GERD, both before and after April 19, 2010.

Dr. Levy testified that "GERD is often a chronic disorder," and therefore "somebody who is diagnosed with GERD often, indeed, has reflux on multiple occasions," and that plaintiff had various characteristics that increased his risk for GERD, including a hiatal hernia, obesity, chronic obstructive pulmonary disease, and a history of smoking cigarettes. Levy Dep. at 68:07-69:12; see also id. at 69:17-70:12 ("A: Chronic obstructive pulmonary disease, history of smoking cigarettes and to the extent he did lie down after meals, . . . all the things being equal, increase the likelihood of GERD."). Dr. Levy also stated that plaintiff's history of GERD indicated that, prior to his inhalation of the product, he had "some abnormalities with [his] lower esophageal sphincter" because "the normal contraction of the lower esophageal sphincter is a major reason why the stomach contents stay in the stomach and ultimately go down lower into the gastrointestinal tract, as opposed to abnormally regurgitating up to the esophagus and potentially regurgitating as far as the larynx." Levy Dep. at 68:07-11. Plaintiff's medical

records show that: (1) plaintiff was diagnosed with esophageal reflux in October 2001 (his symptoms were described as "chest pain which had begun earlier in the day after eating a donut and drinking coffee[,] . . . culminating in difficulty breathing"), Tomaino Dec. Ex. I; (2) an esophogram showed a "small hiatal hernia" in October 2001, id.; (3) plaintiff was referred to a gastroenterologist in October 2001, id.; (4) plaintiff was seen at the emergency room in February 2005, complaining of sharp burning and indigestion, Levy Report at 5; (5) in January 2008, plaintiff was diagnosed with GERD and prescribed Prevacid, Tomaino Dec. Ex. J.; and (6) plaintiff was prescribed Protonix in February 2005, id. Ex. L, and January 2009, id. Ex. M.

Dr. Levy responded to the potential alternative causes of plaintiff's LPR as follows:

> A: . . . [He] had GERD diagnosed as early as 2001. His exposure to peppermint oil in the Ecosmart product exacerbated his reflux of stomach contents into his esophagus up to his larynx, which he apparently did not have before causing the LPR.
>
> Q: If he had GERD before this, though, on prior occasions, stomach acid would come up the esophagus and could also affect the larynx as well, correct?
>
> A: I don't understand your question. I don't recall his having evidence of stomach acid coming up his esophagus and affecting his larynx prior to April 2010.
>
> Q: It could; if you have GERD, it could do that, correct?
>
> A: GERD, that is the reflux of stomach contents of the esophagus, indeed can come up to the larynx and cause a laryngeal disorder, which he indeed had after exposure to the Ecosmart product in April of 2010.
>
> Q: You will agree, someone who has GERD, a long history of GERD, and experiences it for over a course of a number of years, they could suffer damage to the larynx area and vocal cord area, correct; that's commonly known in medicine, do you agree?
>
> A: . . . I do understand that reflux of stomach contents can damage the larynx, as indeed has occurred in this case. . . . [A]s far as I could determine in the medical record, there were only two instances where I saw there were medical encounters in which Mr. Mallozzi was diagnosed with or treated for GERD prior to the exposure to the Ecosmart product in April of 2010; that being in 2001 and in

> 2005. . . . [T]here was also an encounter in 2008 where he indicated, or at least part of the assessment was that he had GERD. Those are the only three medical encounters that I recall in which GERD was specifically mentioned. There may have been others, but those are the only ones that I can recall.

Levy Dep. at 30:15-34:16. It appears from this testimony that Dr. Levy's only basis for excluding plaintiff's GERD as a cause of his LPR is the absence of medical records specifically indicating that plaintiff's reflux irritated his larynx prior to April 19, 2010. Given plaintiff's extensive history of serious reflux problems, this is not a reliable basis for Dr. Levy's conclusion that plaintiff's GERD could not have caused LPR or that plaintiff's reflux could not have reached his larynx but for his exposure to the product. Therefore, Dr. Levy has failed to "provide a reasonable explanation for dismissing" chronic GERD as the cause of plaintiff's injuries. Israel, 2006 WL 3196956, at *5.

4. MSDS

Plaintiff argues that Dr. Levy's opinion is supported by defendant's own Material Safety Data Sheet ("MSDS"). Pl. Memo. at 12. The MSDS warns that users should "[a]void breathing spray mists" because the product "is made from plant oils, some individuals may be sensitive to the fragrance[, and] . . . [i]nhalation of the vapor may cause irritation of nasal passages and/or dizziness," and that "[i]ngestion of th[e] product could result in irritation of the gastrointestinal tract, headache or nausea." Levine Dec. Ex. 1. Reliance upon an MSDS is not justified unless the expert has examined and agrees with the clinical basis for the MSDS, and there is no indication that Dr. Levy performed such an examination. See, e.g., Moore v. Ashland Chem. Inc., 151 F.3d 269, 278 (5th Cir. 1998) (holding that an MSDS has limited scientific value when it is not known what tests were conducted in generating the MSDS); Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1209 (8th Cir. 2000) (holding that the product's MSDS indicating that

breathing dust may irritate the nose and throat and aggravate respiratory diseases was not a sufficient basis for an expert opinion where the expert did not rely upon the MSDS and "nothing in the record demonstrate[d] what scientific tests or information [the manufacturer] used to generate its MSDS"); Ingram v. Solkatronic Chem., Inc., No. 04-CV-0287, 2005 WL 3544244, at *6 (N.D. Okla. Dec. 28, 2005) (holding that the expert's reliance upon an MSDS was not reliable since the expert "knew nothing about the source of the information contained in the MSDS" and "[w]hen an expert purports to offer an opinion based upon his review of existing literature, it is . . . critical [that] the proposed expert carefully review the methodology utilized by the scientist conducting the study to ensure the quality of the assumptions and data therein"). Furthermore, although the warnings in the MSDS are consistent with the scientific literature indicating that peppermint oil may have adverse effects on the gastrointestinal tract, they clearly do not provide a basis for Dr. Levy's specific opinion that inhalation of a substance containing one percent (1.00%) peppermint oil can cause LPR.[8]

IV. Conclusion

For the foregoing reasons, plaintiff has failed to demonstrate that Dr. Levy's testimony meets the reliability requirements of Rule 702 and Daubert, and the testimony is therefore inadmissible. Without Dr. Levy's expert testimony, plaintiff cannot establish that the product was the proximate cause of plaintiff's injuries. See Hollman, 2013 WL 864538, at *5 ("[I]f the expert testimony is excluded as inadmissible under the Rule 702 framework articulated in

[8] Plaintiff also appears to argue that Dr. Levy's opinion is supported by plaintiff's treating physicians' opinions on causation. "[W]hen [a] treating physician seeks to render an opinion on causation, that opinion is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." Davis v. Novartis Pharm. Corp., 857 F. Supp.2d 267, 280 (E.D.N.Y. 2012) (internal quotation marks omitted). Therefore, the deficiencies in Dr. Levy's testimony cannot be overcome by his reliance upon causation opinions of plaintiff's treating physicians that have not been shown to satisfy the requirements of Rule 702.

Daubert and its progeny, the summary judgment determination is made by the district court on a record that does not contain that evidence. Such an analysis must be conducted even if precluding the expert testimony would be outcome determinative.") (citation omitted); Raskin v. Wyatt Co., 125 F.3d 55, 66 (2d Cir. 1997) ("Because the purpose of summary judgment is to weed out cases in which there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law, it is appropriate for district courts to decide questions regarding the admissibility of evidence on summary judgment.") (internal quotation marks, citation and alteration omitted). Accordingly, defendant's motion for summary judgment [Docket Entry No. 16] is granted, and the complaint is dismissed with prejudice. The Clerk of Court is respectfully directed to close this case.

SO ORDERED.

s/ Sandra J. Feuertein

SANDRA J. FEUERSTEIN
United States District Judge

Dated: May 31, 2013
Central Islip, New York